IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Robert James TRIBE	
Serial No. 09/920,728	Art Unit: 3763
Filed: August 3, 2001	Examiner: DeSanto, Matthew F
For: SYRINGE PUMPS	Atty Docket: 0100/0131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES OR IN A NAFTA OR WTO MEMBER COUNTRY TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)

PURPOSE OF DECLARATION

1. This declaration is to establish completion of the invention of this application in

the United States

the NAFTA country (name of country)

X the WIPO country (Great Britain)

at a date prior to June 29, 2000 that is the effective date of the prior art

publication

X patent Ford (US 6,551,277), and

patent publication

other

that were cited by the

X examiner.

applicant.

2. The person making this declaration is (are):

X the inventor(s).

only some of the joint inventor(s) (and a suitable excuse is attached for failure of the omitted joint inventor(s) to sign)

the party in interest (and a suitable explanation as why it is not possible to produce the declaration of the inventor(s) is attached)

FACTS AND DOCUMENTARY EVIDENCE

3. To establish the date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:

(check all applicable items below)

sketches

blueprints

photographs

reproduction(s) of notebook entries

model

supporting statement(s) by witness(es) (where verbal disclosures are the evidence relied upon)

Interference testimony

X disclosure documents (Internal company design specification)

4. From these documents and/or models, it can be seen that the invention in this application was made

on

X at least by the date of June 28, 2000 which is a date earlier than the effective date of the reference.

DILIGENCE

5. Below is a statement establishing the diligence of the applicants, from the time of their conception, to a time just prior to the date of the reference, up to the:

X actual reduction to practice; and/or

X filing of UK 0020060.0 from which Application No. 09/920,728 claims priority.

The invention disclosed in the specification of U.S. Application 09/920,728 was conceived at a date at least prior to June 29, 2000, as evidenced by the hereto attached Internal Company Design Specification (ICDS) relating to the software for the syringe pump disclosed in the '728 specification. From the date at least of the ICDS to the actual reduction to practice of the claimed invention and/or the filing date August 16, 2000 of the application (UK 0020060.0) from which the '728 application claims priority, the inventors were actively and diligently working to put into practice the claimed invention.

TIME OF PRESENTATION OF THE DECLARATION

This declaration is submitted prior to final rejection.

X This declaration is submitted with the first response after final rejection, and is for the purpose of overcoming a new ground of rejection or requirement made in the final rejection.

This declaration is submitted after final rejection. A showing under 37 C.F.R. § 1.116(b) is submitted herewith.

DECLARATION

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Inventor(s)

Full name of sole or first inventor Robert James Tribe
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SIMS GRASEBY

SOFTWARE SPECIFICATION FOR THE 4000 SERIES OF SYRINGE PUMPS

Software Development Manager:	Date: [redacted]
Product Manager:	Date: [redacted]
Project Manager: Andrew Ford	Date: [redacted]
Technical Manager : New Product Development [redacted]	Date: [redacted]

Document No: TS/151-002
Filename: TS 151-002 Issue 6.doc
Issue: 6
Date: [redacted]

Issue	Date	Author	Reason for Issue
Draft	[redacted]	Fiona Roden	For review
A	[redacted]	Fiona Roden	For quotation purposes
B	[redacted]	Fiona Roden	For review
C	[redacted]	Fiona Roden	Following review
1	[redacted]	Chris Pickles, Fiona Roden	Following issue of other specifications and comments from VEGA. Safety requirements added, system alarms expanded.
1A	[redacted]	Chris Pickles	Requirement numbers (as hidden text) added to document in the version that was uploaded into the RTD (by VEGA).
1B	[redacted]	VEGA	Document updated to incorporate all RCFs, Addendums and Resolved Issue texts.
1C	[redacted]	VEGA/Graseby	Document reviewed and updated.
2	[redacted]	VEGA/Graseby	Released following re-baselining activity at VEGA. Note document not formerly released.
2A	[redacted]	VEGA/Graseby	Released following informal review changes
3	[redacted]	VEGA/Graseby	Released following review for inclusion in contract. CD/ECR ref.: ECR 0403
4	[redacted]	VEGA/Graseby	Section 4 updated following review. CD/ECR ref.: ECR 0410
5	[redacted]	VEGA	Issue incorporates RCFs 351.01, 357.01, 359.01, 360.01, 360.02, 361.01, 366.01, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 620, 621, 622, 623, 624, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 638, 639, 640, 641, 642, 643, 644 & 645. CD/ECR ref.: ECR 0441
6	[redacted]	VEGA	Issue incorporates RCFs 367.01, 369.01, 371.01, 373.01, 375.01, 377.01, 379.01 380.01, 382.01, 384.01, 385.01, 386.01, 378.02,

			374.01, 374.02, 374.03, 383.01, 389.01, 391.01, 392.01, 393.01, 396.01, 399.01, 403.01 & 406.01, 407.01. CD/ECR ref.: ECR 0451

Contents

23. OCCLUSION DETECTION

A block in the infusion line will cause a build up of pressure on the pusher side of the blockage. This can be detected through an increase in pressure detected on the dry-side sensor, or using the in-line sensor when fitted. A low pass filter (i.e. averaging), which smoothes the signal, will be used to ensure that one-off high occlusion readings do not cause an occlusion alarm. On detection of an occlusion, the pusher is 'backed off' to ensure that when the blockage is cleared, a large dose is not administered to the patient.

[2074 Occlusion detection shall be performed when Running.] [2073 If the optional in-line pressure sensor is fitted then the in-line pressure sensor shall be used to detect occlusions using the occlusion pressure limit as setup by the user in screen figure 3-2.] [1851 If the in-line pressure sensor is not fitted then the dry side pressure sensor shall be used to detect occlusions using the occlusion pressure limit as setup by the user in screen figure 3-1.]

This means that occlusion detection using the dry-side is suppressed when the in-line sensor is being used. However, the dry-side is used to back-up the operation of the in-line sensor in the following way: [1206 If the in-line measured pressure is beneath the occlusion threshold, but the dry-side pressure exceeds level 5, an occlusion alarm shall result.]
An occlusion may be detected by comparing the sensor reading with the set occlusion limit.
[1115 On detection of occlusion, the pump must stop infusing and generate an occlusion alarm.]

23.1 In-line Pressure Sensing

[1207 When running, an in-line pressure sensor pressure reading should be obtained at least once every 5 seconds.]
[1116 On detection of an occlusion, the pusher should be 'backed off' until either the pressure reading (using 16x rolling average) has fallen to less than 10% of the occlusion pressure limit, or 200 motor steps have been taken.]

23.2 Dry Side Occlusion Sensing

[1194 When running, a reading should be obtained of the pusher force at least every 5 seconds.]

Note that the force required for each of the occlusion levels will be dependent on the diameter of the syringe loaded. [2075 The software shall identify the 'level' from the syringe nominal volume and sensor reading as defined in Table 23-1.]

	2ml top	2/3ml	5ml	10ml	20 / 25ml	30ml	50 ml	Display	Level
Less than	0.7	1.4	2.6	3.8	6.7	8.6	13.5	0 bar	0.0
Equal to or greater than	0.7	1.4	2.6	3.8	6.7	8.6	13.5	1 bar	0.1
Equal to or greater than	1.0	2.0	3.7	5.4	9.6	12.1	19.0	2 bar	0.2
Equal to or greater than	1.3	2.6	4.8	7.0	12.4	15.7	24.5	3 bar	1.0
Equal to or greater than	1.6	3.2	5.9	8.7	15.3	19.3	30.0	4 bar	1.1
Equal to or greater than	1.9	3.8	7.0	10.3	18.1	22.8	35.5	5 bar	1.2
Equal to or greater than	2.1	4.3	8.1	11.9	21.0	26.4	41.0	6 bar	2.0
Equal to or greater than	2.4	4.9	9.3	13.5	23.8	30.0	46.4	7 bar	2.1
Equal to or greater than	2.7	5.5	10.4	15.1	26.7	33.5	51.9	8 bar	2.2
Equal to or greater than	3.0	6.1	11.5	16.7	29.5	37.1	57.4	9 bar	3.0
Equal to or greater than	3.3	6.7	12.6	18.3	32.4	40.7	62.9	10 bar	3.1
Equal to or greater than	3.6	7.3	13.7	19.9	35.2	44.2	68.4	11 bar	3.2
Equal to or greater than	3.9	7.9	14.8	21.6	38.1	47.8	73.9	12 bar	4.0
Equal to or greater than	4.2	8.5	15.9	23.2	40.9	51.3	79.4	13 bar	4.1
Equal to or greater than	4.5	9.1	17.0	24.8	43.8	54.9	84.9	14 bar	4.2
Equal to or greater than	4.8	9.7	18.1	26.4	46.6	58.5	90.4	15 bar	5.0

Table 23-1

Notes to Table 23-1:

1. The body of the table shows the figure the force must be equal to or exceed to display a given number of bars
2. The TOP 2ml syringe is an exception in that it requires a separate column.
3. The level referred to in the right hand column of the table is that displayed as 'current pressure reading' on Figure 3-1 of the Software Specification (note the value shown on figure 3-1 is illustrative only).

4. The highest number of bars will always be displayed, e.g. a force of 7N with a 3ml syringe will display 10 bars.

[2076 On detection of an occlusion, the pusher should be 'backed off' until either the force reading (using 16x rolling average) has fallen to less than 10% of the occlusion force limit, or 200 motor steps have been taken.]